PEDIATRIC FORMULA AND METHODS FOR PROVIDING NUTRITION AND IMPROVING TOLERANCE

FIELD OF THE INVENTION

The invention relates to a pediatric formula, and particularly relates to enhancing the tolerance of pediatric patients fed the formula. Pediatric patients include both infants (children 12 months of age or less) and children (children more than 12 months of age but less than 13 yrs of age). (Therefore, all infants are children, but not all children will be infants.) More specifically, the invention is a pediatric formula comprising xanthan gum that has been found effective in increasing tolerance in patients fed such a formula. The invention is also a method of providing nutrition and a method of improving tolerance comprising administering an effective amount of a pediatric formula comprising xanthan gum.

BACKGROUND OF THE INVENTION

Pediatric formulas may be classified into three general types based on the type of protein: intact protein-based, hydrolyzed protein-based, and free amino acid-based. (Pediatric formulas encompass infant formulas and formulas intended for children one year and older.) Commercial pediatric formulas may also contain, in addition to a protein source, carbohydrates, lipids, vitamins and minerals. Free amino acids are currently utilized as the pediatric source in pediatric formulas (EleCare™, Ross Products Division of Abbott Laboratories) intended for children one year and older who have one or more of the following: problems digesting and absorbing regular foods, severe food allergies, gastrointestinal tract problems, or other conditions in which an elemental diet is needed.

Many pediatric patients experience intolerance to certain formulas (formula intolerance). The terms intolerance and formula intolerance are used interchangeably herein. Intolerance is a non-immune system associated reaction and may be evidenced by behavior or stool or feeding pattern changes such as increased spit-up or vomiting, an increased number of stools, more watery stools, and increased fussiness as compared to normal infants who tolerate formula well. Intolerance is most often indicated by gastrointestinal symptoms (e.g. emesis, stool patterns and gas) as well as behavioral characteristics (e.g. acceptance of formula, fussing and crying). In clinical study settings such behavior may be cause for parents to remove their infants from a particular study. Infants removed from a study because of such behaviors are referred to as exits for intolerance. In a non-clinical setting such behavior often causes parents to switch formulas.

Intolerance can be contrasted with the allergic-type reactions some infants exhibit to certain formulas. These allergic-type reactions are immune system associated, and may be caused by the infant's sensitivity to the protein present in the formula. Many infants who exhibit allergies or sensitivities to intact (whole) proteins, such as those in intact cow's milk protein or intact soy protein isolate-based formulas, are able to tolerate extensively hydrolyzed protein. (Hydrolysate formulas (also referred to as semi-elemental formulas) contain protein that has been hydrolyzed or broken down into short peptide fragments and amino acids and as a result is more easily digested by all infants.) These immune system associated allergies or sensitivities often result in cutaneous, respiratory or gastrointestinal symptoms such as vomiting and diarrhea. Infants who exhibit reactions

to intact protein formulas often will not react to hydrolysate formulas because their immune system does not recognize the hydrolyzed protein as the intact protein that causes their symptoms. Infants who exhibit immune system associated reactions to formulas may also exhibit non-immune system associated reactions (formula intolerance), as previously described.

Many different pediatric formulas are in existence. Much of the previous focus in the art has been on the physical stability of the formulas, and concurrent processing or manufacturing concerns.

U.S. Pat. No. 5,192,577 to Masson discloses and teaches the use of xanthan gum in a nutritional formula but only as a stabilizer and specifically limits that use to formulas that use kappa carrageenan in combination with the xanthan gum. Masson deals primarily with the physical stability of the nutritional formula disclosed therein and does not address the problem of intolerance exhibited by patients fed the formula.

U.S. Pat. No. 5,472,952 to Smidt et al. relates to nutritionally complete food compositions which contain partially hydrolyzed pectin for the management of diarrhea. The use of xanthan gum as an emulsifier or stabilizer is disclosed but no teaching of the amount of xanthan gum is provided.

U.S. Pat. No. 5,681,600 to Anfinone et al. discloses use of xanthan gum in a nutritional formula but teaches that such use of xanthan gum is unacceptable because of unacceptable calcium delivery resulting from use of formulas comprising xanthan gum.

U.S. Pat. No. 4,670,268 to Mahmoud discloses an enteral nutritional hypoallergenic nutritional formula which may contain xanthan gum as a stabilizer but fails to provide any teaching of effective amounts of xanthan gum for that purpose.

U.S. Pat. No. 5,919,512 to Montezinos discloses the use of xanthan gum as a stabilizer in a flavoricloud emulsion such as is present in dilute juice and tea beverages. The emulsion disclosed therein contains no protein and thus, would be unsatisfactory for use as a pediatric formula.

U.S. Pat. No. 5,597,595 to DeWille et al. discloses the use of xanthan gum as an emulsion stabilizer in a low pH beverage fortified with calcium and vitamin D.

U.S. Pat. No. 5,817,351 to DeWille et al. discloses the use of xanthan gum as a stabilizer in low pH beverages that are calcium fortified. The beverages disclosed therein contain no fat and protein and would be unsuitable as a complete nutritional source.

U.S. Pat. No. 5,609,897 to Chandler et al. discloses the use of xanthan gum in a soft drink like powdered beverage that has been fortified with calcium and vitamin D.

U.S. Pat. No. 5,858,449 to Crank et al. discloses the use of xanthan gum in an isoflavone-enriched soy-based frozen dessert.

In general, the prior art nutritional formulas completely fail to address the problem of intolerance. Thus, there is an unmet need for a formula that is more readily tolerated by pediatric patients who exhibit symptoms of intolerance. A formula that is better tolerated will result in behavior more similar to that displayed by normal pediatric patients who tolerate formula well.

SUMMARY OF THE INVENTION

The present invention provides an improved pediatric formula and methods for providing nutrition and increasing the tolerance of children fed the formula. (As used herein,